

Clinical Trial Protocol

Iranian Registry of Clinical Trials

01 Jun 2026

The Effect of Carina Anesthesia with Topical Lidocaine in Endotracheal Suction on Hemodynamic parameters and bucking in Adult Patient After Cardiac Surgery

Protocol summary

Study aim

Determining the effect of Karina anesthesia by topical administration of lidocaine on endotracheal suctioning on hemodynamic parameters and strain in adult patients after heart surgery

Design

Clinical trial with control group, double-blind, randomized, phase 2 and 3 on 64 patients. Random number table was used for randomization.

Settings and conduct

The place is Shahid Rajaei Heart Hospital. endotracheal suctioning is performed after the intervention. Changes in hemodynamic and bucking indices are checked 2 minutes before and during and 2 minutes after endotracheal suctioning. The patient and the recorder are kept blind.

Participants/Inclusion and exclusion criteria

entrance: 1. Being in the age range of 18 to 65 years 2. Patients undergoing heart surgery who have undergone one of the following surgeries: coronary, valve, or both. 3- Having a full level of consciousness (15/15) before admission for surgery. 4- Having stability in the hemodynamic range No entry: 1- No airway abnormalities or unusual use of endotracheal tubes 2. No history of lidocaine allergy

Intervention groups

4 cc of 2% lidocaine in the target group and 4 cc of normal saline 0.9% in the control group is apply into the trachea and then the trachea is sucked.

Main outcome variables

Hemodynamic indicators; Cough reflex (bucking)

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20201011048991N1**

Registration date: **2020-12-19, 1399/09/29**

Registration timing: **registered_while_recruiting**

Last update: **2020-12-19, 1399/09/29**

Update count: **0**

Registration date

2020-12-19, 1399/09/29

Registrant information

Name

Hoda Abedi

Name of organization / entity

Shahid Rajaei Cardiovascular Research and Therapeutic Training Center

Country

Iran (Islamic Republic of)

Phone

+98 21 2392 3312

Email address

abedi.hoda.ha@gmail.com

Recruitment status

Recruitment complete

Funding source

Expected recruitment start date

2020-11-10, 1399/08/20

Expected recruitment end date

2020-12-20, 1399/09/30

Actual recruitment start date

empty

Actual recruitment end date

empty

Trial completion date

empty

Scientific title

The Effect of Carina Anesthesia with Topical Lidocaine in

Endotracheal Suction on Hemodynamic parameters and bucking in Adult Patient After Cardiac Surgery

Public title

"The effect of local anesthesia of carina in suction on hemodynamic and physiological parameters"

Purpose

Supportive

Inclusion/Exclusion criteria

Inclusion criteria:

consent to participate in the study Having a full level of consciousness (15/15) before admission for surgery Having stability in the patient's hemodynamic range Patients who need suction due to accumulation of secretions

Exclusion criteria:

No history of lidocaine allergy Absence of any airway abnormalities or the use of unusual airway endotracheal tubes

Age

From **18 years** old to **65 years** old

Gender

Both

Phase

2-3

Groups that have been masked

- Participant
- Outcome assessor

Sample size

Target sample size: **64**

Randomization (investigator's opinion)

Randomized

Randomization description

In this study, random allocation is done in block form. Groups are divided into 8 groups of 8. The target group is named with the letter A and the control group with the letter B. Randomization was performed individually with statistical software. In each block, 4 positions are assigned to A and 4 positions to B. Each of these letters was assigned to a project participant in the order recorded in the block table. Depending on whether it was A or B, lidocaine or normal saline was used during suctioning and the data were recorded.

Blinding (investigator's opinion)

Double blinded

Blinding description

In this study, the study participant (patient) and the data recorder were kept blind. The procedure is that one nurse is aware of which group the patient is in, and the second nurse writes down the data without knowing the patient group.

Placebo

Used

Assignment

Parallel

Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee

Ethics Committee of Shahid Rajaei Cardiovascular Research and Training Center

Street address

Rajaei Heart Center, Valiasr St

City

Tehran

Province

Tehran

Postal code

19969 11151

Approval date

2020-11-07, 1399/08/17

Ethics committee reference number

IR.RHC.REC.1399.089

Health conditions studied

1

Description of health condition studied

tracheal suction

ICD-10 code

ICD-10 code description

Primary outcomes

1

Description

Hemodynamic parameters

Timepoint

2 minutes before and during and 2 minutes after tracheal suction

Method of measurement

Cardiopulmonary monitoring devices

2

Description

bucking in Intubated patient

Timepoint

2 minutes before and during and 2 minutes after tracheal suction

Method of measurement

Mild (less than 3 times), moderate (between 3 and 5 times), severe (more than 5 times)

Secondary outcomes

empty

Intervention groups

1

Description

Intervention group: 4 cc of 2% lidocaine are apply directly into the carina just before suctioning the trachea.

Category

Prevention

2

Description

Control group: 4 cc of 0.9% Normal saline are apply directly into the carina just before suctioning the trachea.

Category

Placebo

Recruitment centers

1

Recruitment center

Name of recruitment center

Shahid Rajaei cardiovascular center

Full name of responsible person

Hoda Abedi

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Sponsors / Funding sources

1

Sponsor

Name of organization / entity

Rajaei Heart Center

Full name of responsible person

Fateme Shima Hadipoorzade

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

Yes

Title of funding source

Rajaei Heart Center

Proportion provided by this source

20

Public or private sector

Public

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Academic

2

Sponsor

Name of organization / entity

Rajaei Heart Center

Full name of responsible person

Hoda Abedi

Street address

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Email

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Grant name

Grant code / Reference number

Is the source of funding the same sponsor organization/entity?

No

Title of funding source

Hoda Abedi

Proportion provided by this source

80

Public or private sector

Private

Domestic or foreign origin

Domestic

Category of foreign source of funding

empty

Country of origin

Type of organization providing the funding

Persons

Person responsible for general inquiries

Contact

Name of organization / entity

Rajaei Heart Center

Full name of responsible person

Hoda Abedi

Position

Master student of intensive care nursing

Latest degree

Bachelor

Other areas of specialty/work

Nursery

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Person responsible for updating data**Contact****Name of organization / entity**Shahid Rajaei Cardiovascular Research and
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Position

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Latest degree

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Other areas of specialty/work

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Sharing plan**Deidentified Individual Participant Data Set (IPD)**

Yes - There is a plan to make this available

Study Protocol

Yes - There is a plan to make this available

Statistical Analysis Plan

Yes - There is a plan to make this available

Informed Consent Form

Yes - There is a plan to make this available

Clinical Study Report

Yes - There is a plan to make this available

Analytic Code

Yes - There is a plan to make this available

Data Dictionary

Yes - There is a plan to make this available

Title and more details about the data/document

Shared through email

When the data will become available and for how long

Access period starts 1year after the results are published

To whom data/document is availableResearchers working in academic and scientific
institutions**Under which criteria data/document could be used**

unlimited

From where data/document is obtainable

through email abedi.hoda.ha@gmail.com

What processes are involved for a request to access data/document

1 month after sending the email

Comments

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